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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/937,643 | 01/10/2002 | Nigel C. Phillips | 02811-0161US | 2086 |

23370 7590 04/23/2002

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
SUITE 2800
ATLANTA, GA 30309

[REDACTED] EXAMINER

ANGELL, JON E

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1635

DATE MAILED: 04/23/2002

b

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|-----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/937,643 | PHILLIPS ET AL. | |
| | Examiner | Art Unit | |
| | J. Eric Angell | 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 March 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 26-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 26-59 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 26-59 are pending in the application.

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The amendment filed 3/20/02 misnumbered the new claims as claims 32-65. However, the application only consisted of claims 1-25 (which are now cancelled). Misnumbered claims 32-65 been renumbered 26-59.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 26-35, 38-47, 49-56, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Morales et al. (J. Urology 153:1706-1710; 1995). Morales teaches a method of treating prostate cancer comprising administration of a composition comprising mycobacterial DNA (B-DNA) from *M. phlei* (see p. 1706, first column) and a pharmaceutically acceptable

carrier (such as oil microdroplets; p. 1706 first column) to an animal having prostate cancer in an amount effective to have an antineoplastic effect (i.e. inhibition of proliferation of cancer cells) on prostate cancer in the animal having the cancer (see abstract, Fig. 2); wherein the pharmaceutical acceptable carrier is M. phlei cell wall (p. 1706, first column), the M. phlei DNA is preserved and complexed to the cell wall (note the cell wall would inherently have the cell's DNA preserved and complexed to the cell wall unless the cell wall was specifically treated to remove the DNA with agents such as nucleases), and wherein the prostate cancer contains hormone sensitive cells (e.g. androgens such as testosterone) (see p.1706, first column).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 26-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales et al. (J. Urology 153:1706-1710; 1995) in view of Filion et al. (Blood 90(10), Suppl.1:p.58B; 1997).

Morales teaches a method of treating prostate cancer comprising administration of a composition comprising mycobacterial DNA (B-DNA) from *M. phlei* (see p. 1706, first column) and a pharmaceutically acceptable carrier (such as oil microdroplets; p. 1706 first column) to an animal having prostate cancer in an amount effective to have an antineoplastic effect (i.e. inhibition of proliferation of cancer cells) on prostate cancer in the animal having the cancer (see abstract, Fig. 2); wherein the pharmaceutical acceptable carrier is *M. phlei* cell wall (p. 1706, first column), the *M. phlei* DNA is preserved and complexed to the cell wall (note the cell wall would inherently have the cell's DNA preserved and complexed to the cell wall unless the cell wall was specifically treated to remove the DNA with agents such as nucleases), and wherein the prostate cancer contains hormone sensitive cells (e.g. androgens such as testosterone) (see p.1706, first column).

Morales does not teach that the administration comprises administration of an immunological agent or that the antineoplastic effect is induction of a cytokine, such as IL-12.

Filion teaches that *M. phlei* cell wall complex is an antitumoral agent that induces IL-12 synthesis when injected into mice (p. 58B).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize the method of Morales to induce IL-12 production in animals with prostate cancer since Filion teaches that *M. phlei* cell wall complex can induce IL-12 synthesis, and thus is an immunological agent. An ordinary artisan would have been motivated

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to combine these references to create a method where *M. phlei* complexed cell wall is used to treat prostate cancer by inducing IL-12 production since Filion states, "IL-12 synthesized in response to this DNA [*M. phlei* DNA] may be in part responsible for the antitumor activity of *M. phlei* MCC (Regressin)." (see last line, p. 58B).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
April 20, 2002


JEFFREY FREDMAN
PRIMARY EXAMINER